Remarks

Claims 2, 18, 20, 21 and 24-29 are pending in the present application after entry of this amendment. All previously pending claims, except for claim 20, which was not examined, stand rejected.[1] All other prior pending claims have been cancelled. Claims 24-29 have been newly added. The Specification is objected to in part. The Specification has been amended as requested by the Examiner. Claims 2 and 18 have been amended in the interest of facilitating prosecution and allowance, in order to address specific concerns raised by the Office. Claims 1, 3-5, 11-13, 15, 19, 22, which were withdrawn from consideration by the Examiner in the pending Office action as drawn to non-elected inventions (as part of Restriction Requirements/Election of Species Requirements) have been cancelled without prejudice or waiver of the subject matter contained therein. Claims 6 and 23 have also been cancelled to facilitate prosecution. Claims 24-29 have been newly added. No new matter has been added. It is respectfully submitted that the pending claims define allowable subject matter.

Applicant thanks the Examiner for the telephone interview on February 7, 2011. As indicated by the Examiner, however, Applicant is not providing a separate record of its substance, as the interview did not result in resolution of all issues (but instead, was directed to an oral election of Species). If, after review of the instant Amendments and Arguments, the Examiner believes that the amendments do not place the application in condition for allowance, Applicant respectfully requests the Examiner to call the undersigned to address any remaining concerns.

Pursuant to the Examiner's request, Applicant confirms his election of a specific disease as recited in claim 21 (claim 23 having been cancelled herein). That election, as recited in the Examiner's Examiner-Initiated Interview Summary, is SLE (systemic lupus erythematosus). As further requested by the Examiner at page 2 of the instant Office action (OA, p.2), Applicant identifies claims 2, 18, 20, 21, 24 and 25 as readable on the elected species. Applicant

acknowledges the Examiner's comment that, upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all of the limitations of any allowed generic claim, such as pending claims 2 and 18, as amended, and newly presented claim 24. See OA, at p.2.

The specification has been objected to for asserted lack of antecedent basis in the body of the specification to the recitation in the claims of "a monoclonal antibody". In the Office action (OA, at p.3), the Examiner invited Applicant to amend the specification to provide antecedent basis for the claimed subject matter. Applicant has therefore amended paragraph 11 of the specification to insert the necessary antecedent basis expressly in the specification. Accordingly, Applicants respectfully request that the objection to the specification be withdrawn.

Claims 2, 18, and 21, have been rejected under 25 U.S.C. 112, 1st paragraph, as failing to comply with the written description requirement. The Examiner urges that the recitation of "monoclonal antibody" is inadequate because it does not recite antigen specificity, thus reading on any monoclonal antibody. Applicant respectfully traverses this rejection as applied to the claims as amended herein. Applicant has amended the claims to recite "a monoclonal antibody having specificity for the membrane attack complex (MAC)." Support for this amendment is provided and can be drawn from, *inter alia,* the original specification at paragraphs 11, 12, 18-23, and 38 and the claims. Accordingly, having addressed the Examiner's concern embodied in this rejection, Applicant urges that the rejection is moot, and should be withdrawn. New claims 24-29 track the above-recited claims in this respect, and should be allowed.

Claims 2, 18, and 21 also have been rejected under 25 U.S.C. 112, 1st paragraph, as failing to comply with the enablement requirement. The Examiner again urges that the recitation of "monoclonal antibody" is inadequate because it does not recite antigen specificity. Applicant respectfully traverses this rejection as applied to the claims as amended herein. Applicant has amended the claims to recite "a monoclonal antibody having specificity for the membrane attack

complex." Support for this amendment is as indicated above. The Examiner's suggestions having been specifically addressed, applicant urges that the enablement rejection is therefore now moot.

It should be noted that the technology underlying the preparation, development and use of monoclonal antibodies was first developed nearly forty years ago. That technology has developed to the point that it is now recited in Wikipedia, without protest or exception taken, that: "Given almost any substance, it is possible to produce monoclonal antibodies that specifically bind to that substance." (See Wikipedia text under topic, "Monoclonal Antibodies," posted as on August 25, 2011.) Thus, it is well within the abilities of the ordinary skilled worker in this art to devise monoclonal antibodies that specifically bind to MAC in order to inhibit its binding to circulating immune complex (CIC).[2] However, as discussed further below, the *advisability and value,* of developing such an inhibitor to the MAC-CIC interaction was unknown prior to Applicant's discoveries. Not until Applicant divined that symptoms of diseases and conditions such as SLE may be ameliorated by directly inhibiting the MAC-CIC interaction, was this appreciated. Accordingly, since one skilled in the art would in fact have no difficulty carrying out the claimed invention as disclosed and claimed by applicant, given the decades-long routines and practices of this art, Applicant urges that the claims, as amended, are fully enabled. Therefore, the rejection of the pending amended claims should respectfully be withdrawn. New claims 24-29 track the above-recited claims in this respect, and should be allowed as well.

Claims 2, 18, 2 and 21 are rejected under 35 U.S.C. §102 as being unpatentable over Evans et al. (US Patent No. 6,355,245). Applicants respectfully traverse this rejection for at least the reasons set forth hereafter.

Nothing contained in Evans et al.'s disclosures suggest that the MAC and CIC associate together in a non-covalent manner, that there would be any value in directly inhibiting MAC's

interaction with the CIC, or that the beneficial results obtained by Applicant would be possible. Hence, claims 2, 18 and 21, relate to a different approach, do not "read on" the approach used by Evan's et al., and were not obvious in view of the teachings of Evans et al. In short, the cited art, Evans et al., fails to teach each and every limitations of Applicant's invention as embodied in the claims, as amended. Accordingly, Applicant respectfully urges that the rejection of claims 2, 18, and 21 under Sec. 102 over Evans et al., should be withdrawn.

Applicant notes that claim 18 has been amended to clarify that "identifying" individuals in need was not intended to me merely a mental step – see amended claim 18, above. Claim 18 is therefore not anticipated by Evans et al. for its recitation of this important additional step. Evans et al. did not practice the "identifying" step (and could not as they did not recognize the value of identifying such individuals as they had not discovered, nor been presented with the finding developed regarding the interaction of MAC and CIC by Applicant.

Newly added claims 24-29 track both original claims 2, 18 and 21, as herein amended, regarding antigen specificity, and claim 18 regarding the identifying step, and therefore are patentable for the same reasons discussed above.

Accordingly, Applicants submit that claims 2, 18, 21, and 24-29 are patentable over the prior art and should be allowed without further delay.

In view of the foregoing, it is respectfully submitted that the cited reference neither anticipates (as actually rejected), nor renders obvious (pointed out to avoid unnecessary delay in prosecution herein), the claimed invention and the pending claims in this application are believed to be in condition for allowance. Reconsideration and favorable action is respectfully solicited.

Respectfully Submitted,

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[1] Applicant believes that the Examiner inadvertently withdrew claim 20 from examination, as in fact, it reads on the Group and Species elected by Applicant and had not been previously cancelled. However, in responding to the Office action, Applicant assumed arguendo that the same rejections applicable to the other examined claims might have been lodged by the Examiner against claim 20 if not incorrectly withdrawn from examination. Thus, the Examiner withdrew from examination all pending claims except for 2, 6, 18, 21 and 23, and rejected these claims for the reasons set out in the instant Office action. Claim 20 does not appear to have been examined. Claims 6 and 23 were cancelled in this response together with all other pending, non-examined claims. Claims 24-29 are newly added.

[2] The development of monoclonal antibodies, while routine where the location and purpose is clearly known, can be nearly prohibitively expensive for a small inventor such as Applicant. See, e.g., http://www.globalresearchonline.net/volume1issue2/Article%20017.pdf, (as posted on the Internet as of August 25, 2011), at its first regular paragraph of the manuscript. There it states that the production of a single MAb using hybridoma is quoted for between $8,000 and $12,000. As indicated in this Response to Office action, where such technology is highly predictable and well known to those in the art, requiring such a huge expense clearly unnecessary to the practical practice of the invention, simply to detail a routine procedure for a well-met requirement is unfair and would be dramatic overkill. Applicant does not believe that the Office is requiring such detail, as it is unnecessary to practice the invention without undue experimentation. It is a well-established rule of patent practice that what is routine in the art should be summarily presented.